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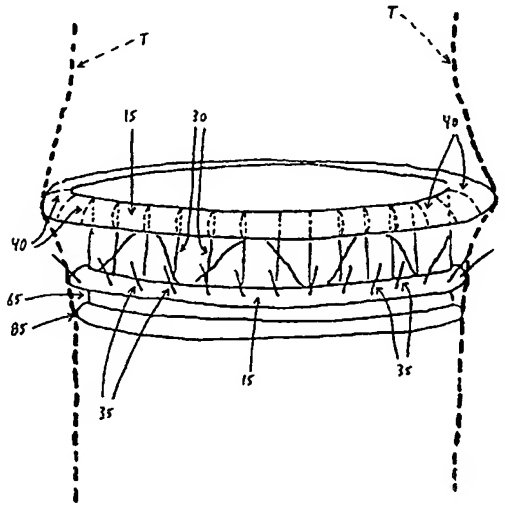
(54) Title: FIXATION BAND FOR AFFIXING A PROSTHETIC HEART VALVE TO TISSUE



(57) Abstract: A fixation band for affixing a prosthetic heart valve within the heart. The fixation band comprises a tubular frame and a tube (15), both having a distal and proximal ends. The tubular frame comprises a plurality of longitudinally-extending members (30) each having a hook (35) on its distal end and fixation means (40) on its proximal end and at least one laterally-extending member for stabilizing the longitudinally-extending members (30). In use, the sewing cuff of prosthetic valve (85) is sutured to the sewing cuff (65) of the fixation band and the apparatus is positioned at the valve seat. The fixation band's tubular frame is then pulled proximally to cause the hooks to pass through the sidewall of the everted tube and into the surrounding tissue. Fixation means (40) are then deployed to secure the proximal end of the fixation band of the tissue.

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FIXATION BAND FOR AFFIXING A PROSTHETIC HEART VALVE TO TISSUE

Reference To Pending Prior Patent Application

This patent application claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/230,756, filed 09/07/00 by John R. Liddicoat for DEVICE AND METHODS FOR THE SUTURELESS IMPLANTATION OF A HEART VALVE (Attorney's Docket No. VIA-11 PROV), which patent application is hereby incorporated herein by reference.

Field Of The Invention

This invention relates to surgical apparatus in general, and more particularly to prosthetic heart valves.

Background Of The Invention

The human heart consists of four chambers: the right atrium for receiving blood from systemic circulation; the right ventricle for receiving blood

from the right atrium and pumping it to the lungs; the left atrium for receiving oxygenated blood from the lungs; and the left ventricle for receiving oxygenated blood from the left atrium and pumping it to systemic circulation.

The human heart also consists of four valves: the tricuspid valve located between the right atrium and the right ventricle; the pulmonary valve located at the output of the right ventricle; the mitral valve located between the left atrium and the left ventricle; and the aortic valve located at the output of the left ventricle.

In some circumstances (e.g., a birth defect, disease, etc.) a natural heart valve may need to be replaced by a prosthetic heart valve. In this situation, sometimes referred to as "on pump" surgery, the patient must be placed on a heart-lung machine and the heart stopped while the defective heart valve is removed and the prosthetic heart valve installed through a major incision made in the wall of the heart. The prosthetic heart valve is typically

sutured in place at the annulus, or seat, of the natural heart valve using a sewing cuff disposed about the circular periphery of the prosthetic heart valve.

While such surgery is typically successful, it is also highly traumatic to the body and the use of the heart-lung machine may raise issues of subtle mental impairment in the near term following surgery.

In view of the trauma associated with a major coronary wall incision and possible subtle mental impairment which may be associated with the use of a heart-lung machine, it has been proposed to effect valve replacement without placing the patient on a heart-lung machine and stopping the heart. See, for example, PCT Patent Application No. PCT/US00/02126, filed 01/27/00 by Gregory Lambrecht et al. for CARDIAC VALVE PROCEDURE METHODS AND DEVICES, published 8/3/00 as PCT Patent Publication No. WO 00/44313. This type of surgery is sometimes referred to as "off-pump", or "beating heart", surgery.

It has been recognized that if a heart valve is to be replaced with "off-pump", "beating heart"

surgery, the incisions made into the vascular system should be as small as possible. However, this can make it difficult to secure the prosthetic heart valve in place, since the prosthetic heart valve is typically sutured to the annulus, or seat, of the natural heart valve, and since suturing (including knot tying) can be difficult to effect through small incisions. This can be particularly true where the incisions may be made into the vascular system at a location remote from the valve seat, e.g., in the superior vena cava in the case of the tricuspid valve, or in the pulmonary artery in the case of the pulmonary valve, or the pulmonary veins in the case of the mitral valve, or the aorta in the case of the aortic valve.

Summary Of The Invention

As a result, one object of the present invention is to provide novel apparatus for quickly, easily and conveniently affixing a prosthetic heart valve in position within the heart.

Another object of the present invention is to provide a novel fixation band for affixing a prosthetic heart valve in position within the heart.

And another object of the present invention is to provide a novel method for affixing a prosthetic heart valve in position within the heart.

These and other objects of the present invention are addressed by the provision and use of a novel fixation band for affixing a prosthetic heart valve in position within the heart.

In one preferred form of the invention, the fixation band generally comprises a tubular frame having a distal end and a proximal end, and a tube having a distal end and a proximal end. The tubular frame comprises a plurality of longitudinally-extending members each having a hook on its distal end and fixation means on its proximal end. The tubular frame also comprises at least one laterally-extending member for stabilizing the longitudinally-extending members relative to one another so as to form the complete tubular frame. The

tube is positioned inside the longitudinally-extending members, with the distal end of the tube being everted back over the aforementioned hooks. A sewing cuff is formed in the tube distal to the distalmost end of the longitudinally-extending members.

In use, a standard prosthetic valve is secured to the distal end of the fixation band by suturing the prosthetic valve's sewing cuff to the fixation band's sewing cuff. Next, the prosthetic valve, with fixation band attached, is advanced to the valve's seat. Then the fixation band's tubular frame is pulled proximally slightly. This action causes the ends of the hooks to pass through the side wall of the everted tube and into the surrounding tissue at the valve's seat, whereby the fixation band, and hence the prosthetic valve, will be fixed against further proximal movement. Next, the fixation band's fixation means are deployed so as to secure the proximal end of the fixation band to the surrounding tissue, whereby the fixation band, and hence the prosthetic valve, will be fixed against distal movement.

In one form of the invention, the fixation means may be deployed by bending them radially outwardly so that they engage the surrounding tissue.

In another form of the present invention, the fixation means may be deployed by removing a restraining device, whereby the fixation means will automatically deploy against the surrounding tissue.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

Fig. 1 is a schematic view of a fixation band formed in accordance with the present invention;

Fig. 2 is a schematic view of the fixation band's tubular frame;

Fig. 3 is a schematic view of the fixation band's tube prior to its assembly with the tubular frame;

Fig. 4 is a schematic view of the complete fixation band shown in Fig. 1;

Fig. 5 is a schematic view showing a prosthetic heart valve secured to the fixation band of Fig. 1;

Fig. 6 is a schematic view showing the assembly of Fig. 5 after deployment of the fixation band's distal hooks;

Fig. 7 is a schematic view showing the assembly of Fig. 6 after deployment of the fixation band's proximal fixation means; and

Fig. 8 is a schematic view showing a restraining device for restraining the fixation band's proximal fixation means.

Detailed Description Of The Preferred Embodiements

Looking first at Fig. 1, there is shown a fixation band 5 which comprises one preferred form of the invention. Fixation band 5 generally comprises a tubular frame 10 and a tube 15.

Tubular frame 10 is shown in greater detail in Fig. 2. Tubular frame 10 generally comprises a distal end 20 and a proximal end 25. Tubular frame 10 comprises a plurality of longitudinally-extending members 30 each having a hook 35 on its distal end, and fixation means 40 (discussed in further detail below) on its proximal end. Tubular frame 10 also comprises at least one laterally-extending member 45 for stabilizing the longitudinally-extending members 30 relative to one another so as to form the complete tubular frame. In one form of the invention, each laterally-extending member 45 extends completely around the circumference of the frame, in the manner shown in Fig. 2. Alternatively, a series of separate laterally-extending members 45 may be used to span the circumference of tubular frame 10. Furthermore, in one form of the invention, laterally-extending member 45 may be in the form of a circular hoop, like the hoop of a barrel, such as the laterally-extending member 47 shown in Fig. 2. Alternatively, and/or in

addition, laterally-extending member 45 may have a serpentine configuration, such as the laterally-extending member 48 shown in Fig. 2.

Tube 15 is, initially, an ordinary straight tube such as is shown in Fig. 3, i.e., it is a hollow structure having a distal end 50, a proximal end 55 and a central lumen 60 extending therebetween. Tube 15 is preferably formed out of material which is easily incorporated in tissue, e.g., Dacron polyester or the like. Tube 15 may be vertically pleated or elastic, whereby to allow the material to stretch radially.

Tube 15 is mounted to tubular frame 10 as follows. First, the distal end 50 of tube 15 is passed, distally, down the interior of tubular frame 10. Then the distal end 50 of tube 15 is everted (Fig. 4) so as to fold it back over, and cover, the hooks 35 of longitudinally-extending members 30.

As this is done, a sewing cuff 65 is formed in tube 15 distal to the distalmost end of longitudinally-extending members 30. Tube 15 may then

be secured in this position, e.g., with sutures 70 maintaining sewing cuff 65 and with sutures 80 holding tube 15 to longitudinally-extending members 30.

In use, a standard prosthetic heart valve 85 (Fig. 5) is secured to the distal end of fixation band 5 by sewing the prosthetic heart valve's sewing cuff 90 to the fixation band's sewing cuff 65. Next, the prosthetic valve 85, with fixation band 5 attached, is advanced to the valve's seat. Then the fixation band's tubular frame 10 is pulled proximally slightly. This action causes the ends of the hooks 35 to pass through the side wall of the everted tube 15 (Fig. 6) and into the surrounding tissue T at the valve's seat, whereby fixation band 5, and hence prosthetic valve 85, will be fixed against further proximal movement. Next, the fixation band's fixation means 40 are deployed (Fig. 7) so as to secure the proximal end of the fixation band to surrounding tissue, whereby the fixation band, and hence the prosthetic valve, will be fixed against distal movement. Where the fixation means 40 are secured to the proximal end of tube 15,

the proximal end of tube 15 will follow the curvature of the deploying fixation means 40, such as is shown in Fig. 7. Alternatively, if fixation means 40 are free to move independently outboard relative to the proximal end of tube 40, either because they are not secured to tube 15 or they extend past the proximal end of the tube, fixation means 40 are free to move separately into the surrounding tissue.

In one form of the invention, fixation means 40 may be deployed by bending the proximal ends of longitudinally-extending members 30 outwardly, e.g., with an annular forming tool or a forceps-type device.

In another form of the invention, fixation means 40 may be deployed by removing a restraining device, e.g., a collar 90 (Fig. 8), whereby fixation means 40 will automatically deploy against the surrounding tissue.

Fixation band 5 may be used to affix prosthetic heart valve 85 to tissue in a conventional on-pump surgical procedure. Alternatively, and more preferably, fixation band 5 may be used to affix

prosthetic heart valve 85 to tissue in a beating heart, off-pump surgical procedure. In this case, the assembled heart valve 85 and fixation band 5 are advanced to the intended valve seat by passing the assembly through an appropriate vascular pathway, e.g., in the case of the aortic valve, by passing the assembly down the aorta.

It should be appreciated that various modifications may be made to the preferred embodiments described above without departing from the scope of the present invention. Thus, for example, in the foregoing description, tubular frame 10 is described as being fully assembled (i.e., laterally-extending member 45 is secured to longitudinally-extending member 30) prior to being joined with tube 15 so as to form the complete fixation band 5. However, it should also be appreciated that longitudinally-extending members 30 and/or the laterally-extending member 45 may be secured to tube 15 prior to being joined to one another.

Furthermore, in the foregoing description, tube 15 is described as being, prior to eversion, an ordinary straight tube. However, if desired, tube 15 could be flared outwardly toward its distal end 50 to facilitate eversion over hooks 35, and/or it could include a radially-extending flange at its distal end to facilitate eversion over hooks 35, where the flange may be formed separately from the main body of the tube.

Still other modifications and variations will be apparent to those skilled in the art in view of the present disclosure, and are considered to be within the scope of the present invention.

What Is Claimed Is:

1. A fixation band for affixing a prosthetic heart valve to tissue, said fixation band comprising:

a body;

a sewing cuff for securing the prosthetic heart valve to the fixation band, said sewing cuff being attached to said body; and

a plurality of radially-expanding members for securing said fixation band to tissue, said plurality of radially-expanding members being attached to said body.

2. A fixation band according to claim 1 wherein said plurality of radially-expanding members comprise at least one hook disposed at a distal end of said body.

3. A fixation band according to claim 1 wherein said plurality of radially-expanding members comprise

fixation means disposed at said proximal end of said body.

4. A fixation band according to claim 3 wherein said fixation means are actuated by bending the same radially outwardly so as to engage the surrounding tissue.

5. A fixation band according to claim 3 wherein said fixation means are adapted to be deployed by removing a restraining device, whereby the fixation means will automatically deploy against the surrounding tissue.

6. A fixation band for affixing a prosthetic heart valve to tissue, said fixation band comprising:

a tubular frame having a distal end and a proximal end, said tubular frame comprising a plurality of longitudinally-extending members each having a hook on its distal end and fixation means on its proximal end, and at least one laterally-extending

member for stabilizing the longitudinally-extending members relative to one another so as to form the complete tubular frame; and

a tube positioned inside said longitudinally-extending members, with the distal end of said tube being everted back over said hooks, and with a sewing cuff being formed in said tube distal to the distalmost end of said longitudinally-extending members.

7. A fixation band according to claim 6 wherein said fixation means are actuated by bending the same radially outwardly so as to engage the surrounding tissue.

8. A fixation band according to claim 6 wherein said fixation means are adapted to be deployed by removing a restraining device, whereby the fixation means will automatically deploy against the surrounding tissue.

9. A prosthetic heart valve assembly comprising:

a prosthetic heart valve comprising a frame, at least one leaflet adapted to open and close relative to said frame, and a sewing cuff attached to said frame;

a fixation band for affixing said prosthetic heart valve to tissue, said fixation band comprising:

a body;

a sewing cuff for securing said prosthetic heart valve to said fixation band, said sewing cuff being attached to said body; and

a plurality of radially-expanding members for securing said fixation band to tissue, said plurality of radially-expanding members being attached to said body;

said prosthetic heart valve being secured to said fixation band by suturing the sewing cuff of said prosthetic heart valve to the sewing cuff of said fixation band.

10. A fixation band according to claim 9 wherein said plurality of radially-expanding members comprise at least one hook disposed at a distal end of said body.

11. A fixation band according to claim 9 wherein said plurality of radially-expanding members comprise fixation means disposed at said proximal end of said body.

12. A fixation band according to claim 11 wherein said fixation means are actuated by bending the same radially outwardly so as to engage the surrounding tissue.

13. A fixation band according to claim 11 wherein said fixation means are adapted to be deployed by removing a restraining device, whereby the fixation means will automatically deploy against the surrounding tissue.

14. A prosthetic heart valve assembly comprising:

a prosthetic heart valve comprising a frame, at least one leaflet adapted to open and close relative to said frame, and a sewing cuff attached to said frame;

a fixation band for affixing said prosthetic heart valve to tissue, said fixation band comprising:

a tubular frame having a distal end and a proximal end, said tubular frame comprising a plurality of longitudinally-extending members each having a hook on its distal end and fixation means on its proximal end, and at least one laterally-extending member for stabilizing the longitudinally-extending members relative to one another so as to form the complete tubular frame; and

a tube positioned inside said longitudinally-extending members, with the distal end of said tube being everted back over said hooks, and with a sewing cuff being formed in said tube distal to

the distalmost end of said longitudinally-extending members;

said prosthetic heart valve being secured to said fixation band by suturing the sewing cuff of said prosthetic heart valve to the sewing cuff of the fixation band.

15. A fixation band according to claim 14 wherein said plurality of radially-expanding members comprise at least one hook disposed at a distal end of said body.

16. A fixation band according to claim 14 wherein said plurality of radially-expanding members comprise fixation means disposed at said proximal end of said body.

17. A fixation band according to claim 16 wherein said fixation means are actuated by bending the same radially outwardly so as to engage the surrounding tissue.

18. A fixation band according to claim 16 wherein said fixation means are adapted to be deployed by removing a restraining device, whereby the fixation means will automatically deploy against the surrounding tissue.

19. A method for affixing a prosthetic heart valve to tissue, said method comprising:

providing a prosthetic heart valve comprising a frame, at least one leaflet adapted to open and close relative to said frame, and a sewing cuff attached to said frame; and providing a fixation band for affixing the prosthetic heart valve to tissue, said fixation band comprising a body, a sewing cuff for securing the prosthetic heart valve to the fixation band, the sewing cuff being attached to the body, and a plurality of radially-expanding members for securing the fixation band to tissue, said plurality of radially-expanding members being attached to the body;

securing the prosthetic heart valve to the fixation band by suturing the sewing cuff of the prosthetic heart valve to the sewing cuff of the fixation band;

positioning the prosthetic heart valve at its valve seat; and

fixing the fixation band to tissue surrounding the valve seat.

20. A method for affixing a prosthetic heart valve to tissue, comprising:

providing a prosthetic heart valve comprising a frame, at least one leaflet adapted to open and close relative to said frame, and a sewing cuff attached to said frame; and providing a fixation band for affixing the prosthetic heart valve to tissue, said fixation band comprising a tubular frame having a distal end and a proximal end, said tubular frame comprising a plurality of longitudinally-extending members each having a hook on its distal end and fixation means on its proximal end,

and at least one laterally-extending member for stabilizing the longitudinally-extending members relative to one another so as to form the complete tubular frame; and a tube positioned inside said longitudinally-extending members, with the distal end of said tube being everted back over said hooks, and with a sewing cuff being formed in said tube distal to the distalmost end of said longitudinally-extending members;

securing the prosthetic heart valve to the fixation band by suturing the sewing cuff of the prosthetic heart valve to the sewing cuff of the fixation band;

positioning the prosthetic heart valve at its valve seat; and

fixing the fixation band to tissue surrounding the valve seat.

21. A fixation band according to claim 6 wherein said tube is flared outwardly at said distal end of said tube.

22. A fixation band according to claim 6 wherein said tube comprises a radially-extending flange at its distal end.

23. A prosthetic heart valve assembly according to claim 14 wherein said tube is flared outwardly at said distal end of said tube.

24. A prosthetic heart valve assembly according to claim 14 wherein said tube comprises a radially-extending flange at its distal end.

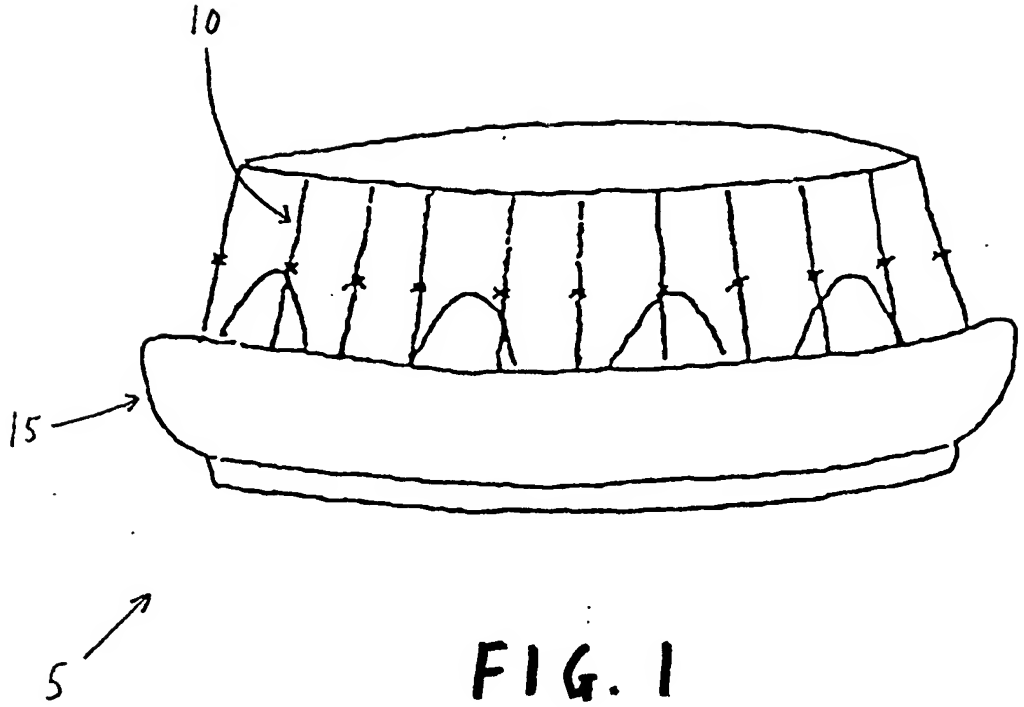

FIG. 1

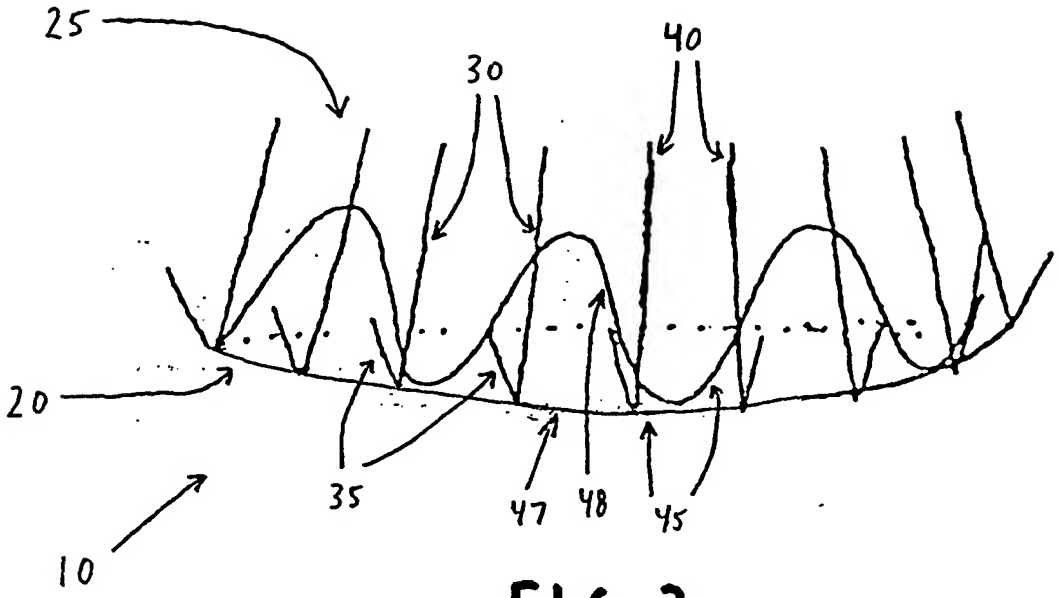

FIG. 2

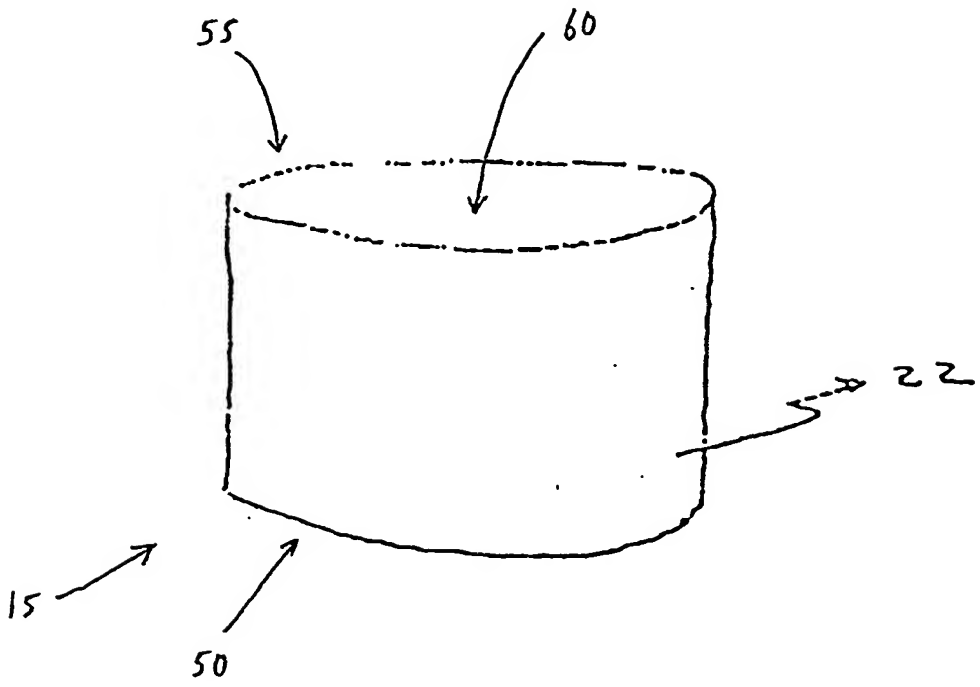

FIG. 3

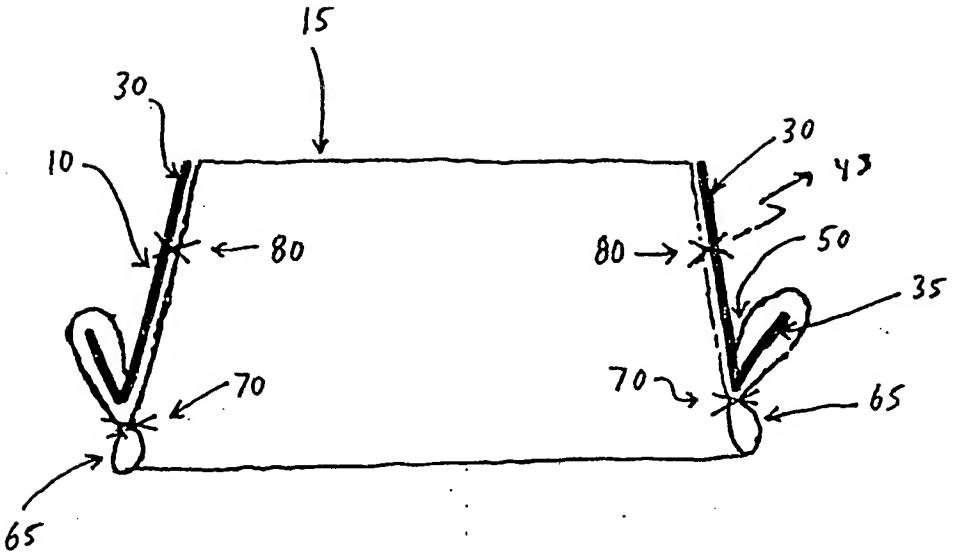

FIG. 4

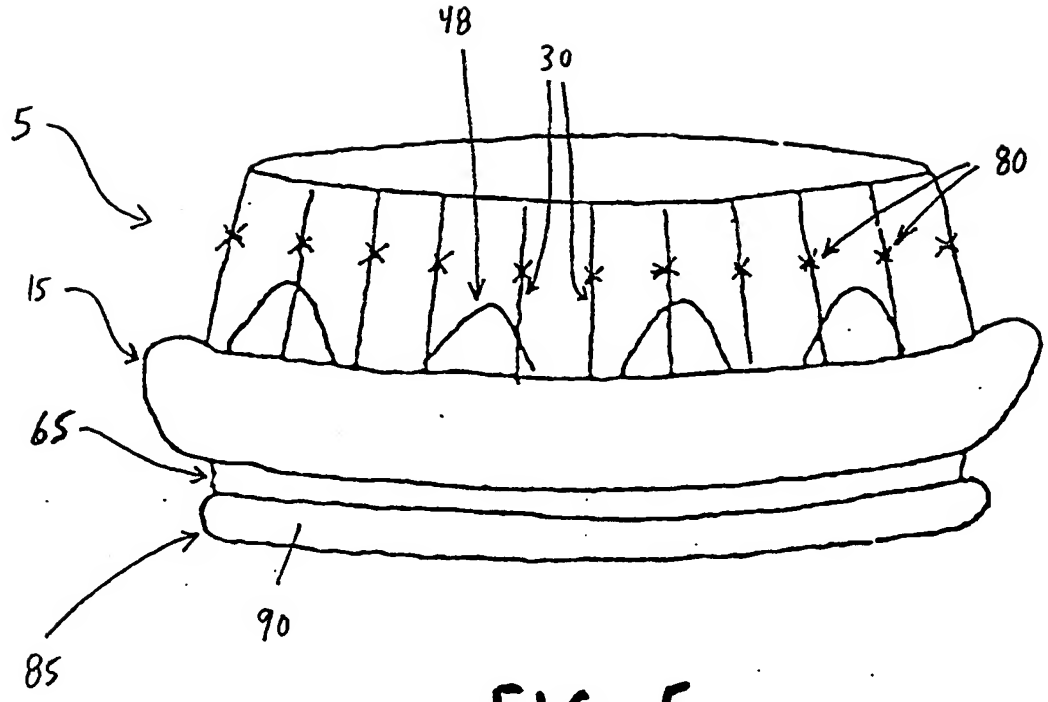

FIG. 5

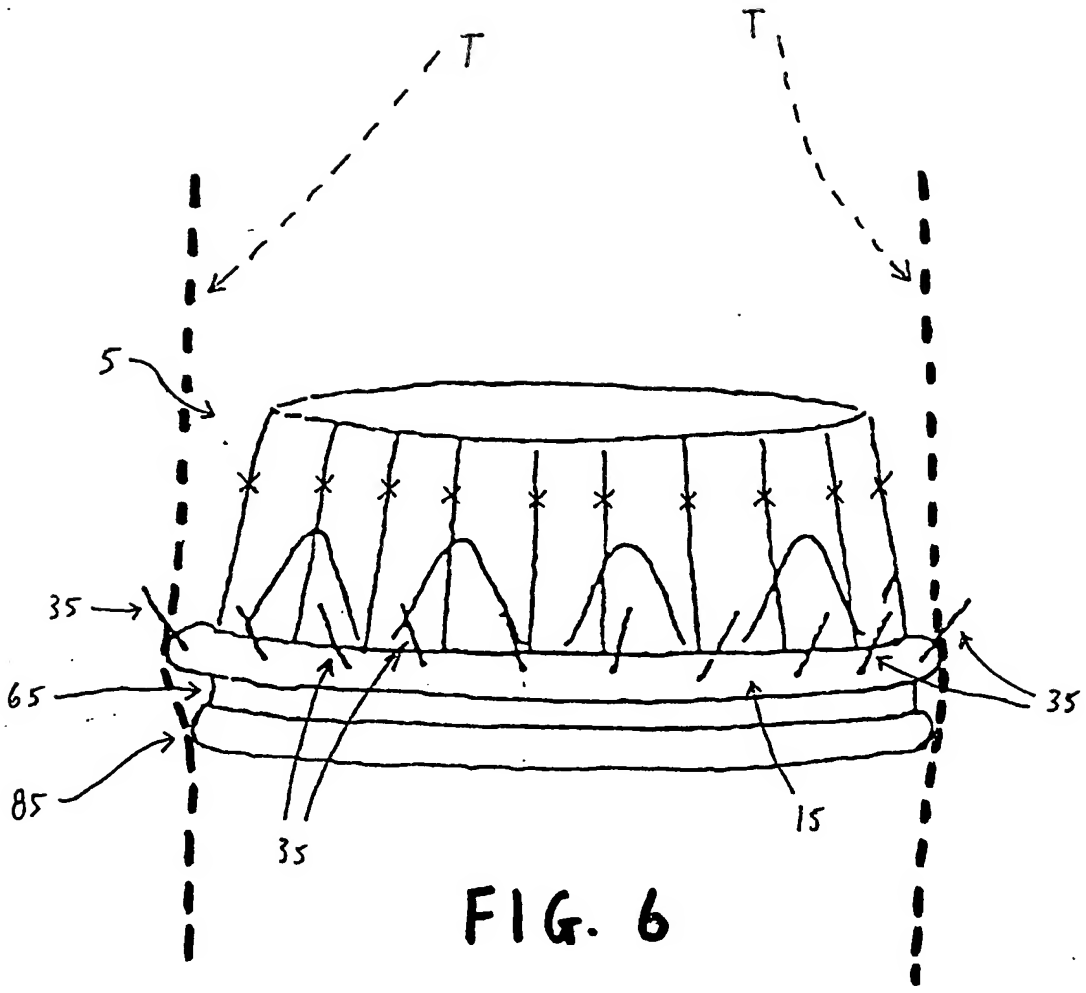

FIG. 6

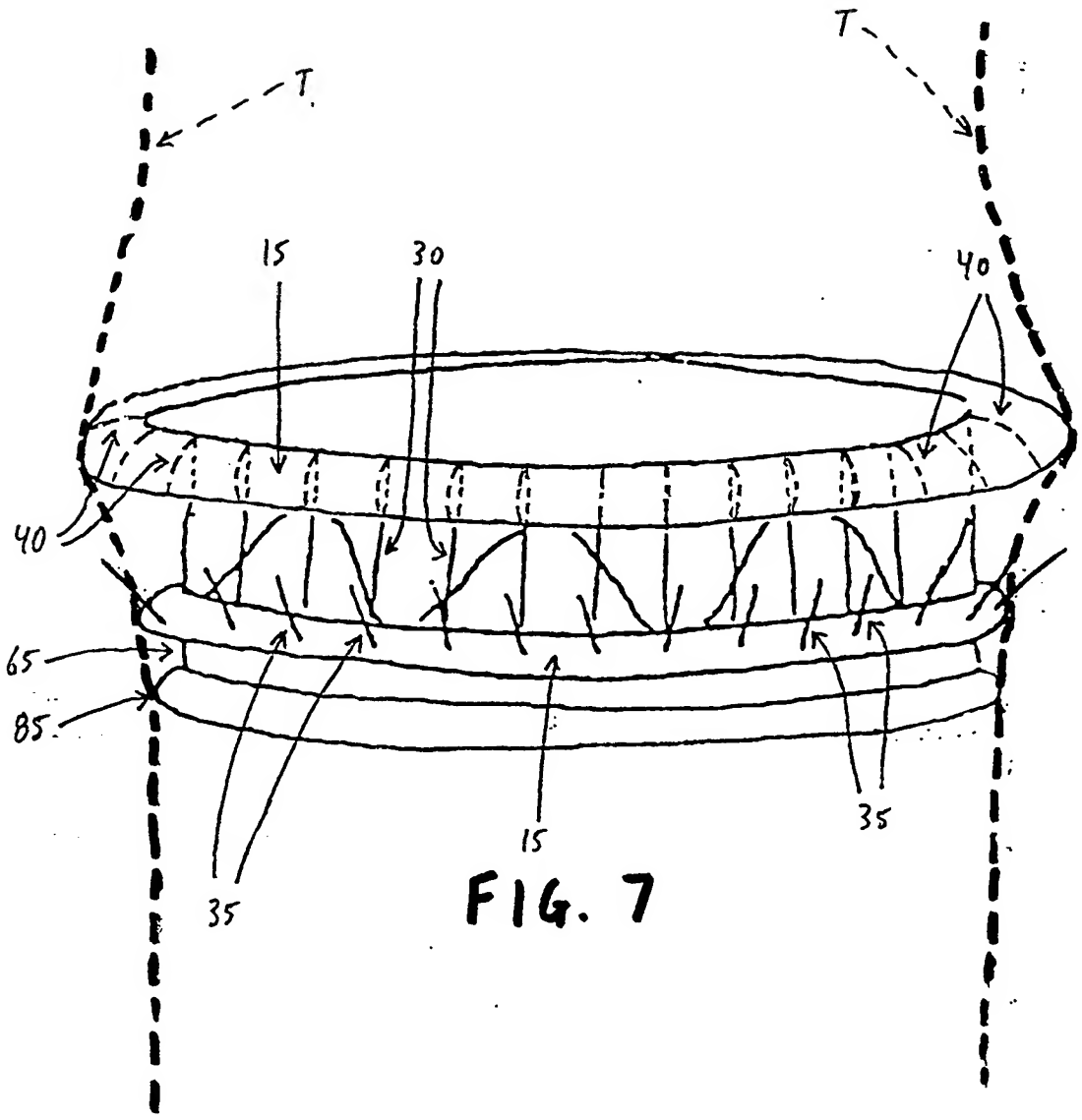

FIG. 7

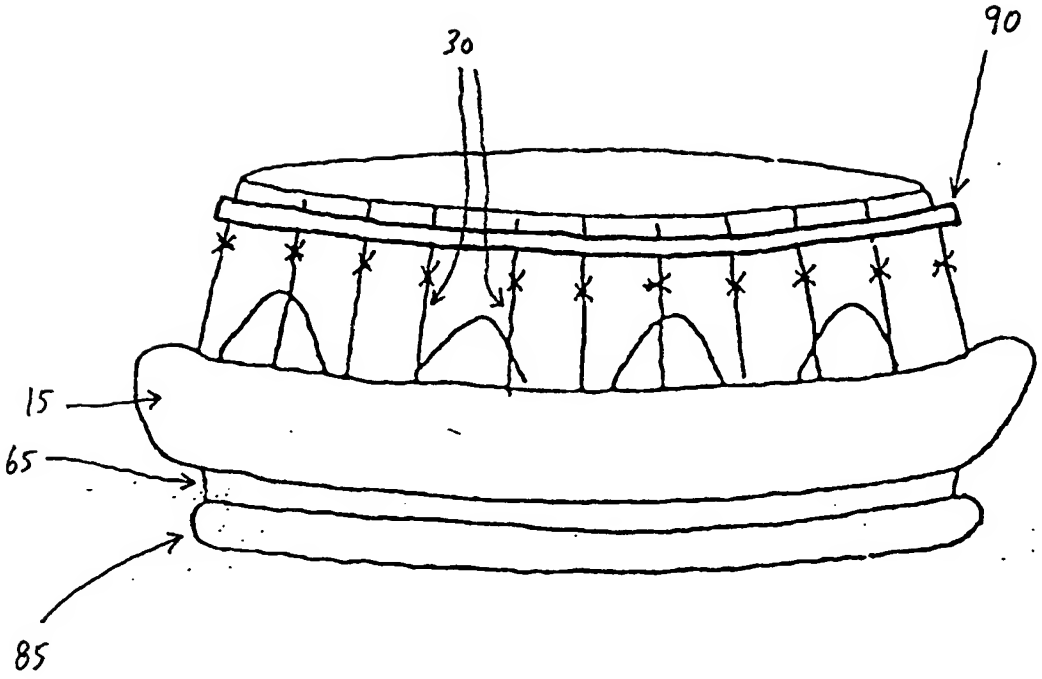

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/25099

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/24
US CL : 623/2.4
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/2.4, 2.41, 2.38, 2.39

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,996,623 A (KASTER) 14 December 1976, col. 1, lines 34-37.	21-24
X --- Y	US 4,506,394 A (BEDARD) 26 March 1985, see figure 1-3 and 6; col. 3, lines 51-53; col. 4, lines 3-8, 20-32, 58-63; col. 5, lines 11-18; col. 8, lines 24-37.	1-4,6,7,9-12,14-17,19,22 -24 --- 5,8,13,18,20,21
Y	US 5,843,179 A (VANNEY et al) 01 December 1998, Figures 1, 10, 17D1; col. 5, lines 10-33; col. 7, lines 16-49.	1-24

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 01 NOVEMBER 2001	Date of mailing of the international search report 25 JAN 2002
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/26099

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, E --- Y, E	US 6,287,339 B1 (VAZQUEZ et al) 11 September 2001, figures 2,4,10; col. 4 . lines 19-35, 44-58, 65-67, col. 5, lines 1-9, col. 9, lines 33-35, col. 12, lines 39-54.	1-3,5,6,8-11,13-16,18-20 --- 4,7,12,17,21-24
A	WO 89/00841 A1 (LILLEHEI et al.) 09 February 1989, pages 6-7.	